

Claims

1. An oral solution comprising mitratapide or a pharmaceutically acceptable salt thereof, a pharmaceutically acceptable solvent wherein mitratapide has a solubility of 5 mg/ml or higher at a temperature of 22°C, a taste modifying agent and an antioxidant.
2. An oral solution as claimed in claim 1 wherein the pharmaceutically acceptable solvent is selected from the group consisting of dimethyl isosorbide, diethylene glycol monoethyl ether, caprylocaproyl macrogol-8 glyceride, propylene glycol monolaurate, polyethyleneglycol 200, polyethyleneglycol 300 and polyethyleneglycol 400, and mixtures thereof, or mixtures of polyethylene glycols (PEGs) having an average molecular weight higher than 400 with PEGs having an average molecular weight lower than 400 so that the mixture thereof is liquid at room temperature.
3. An oral solution as claimed in claim 2 wherein the pharmaceutically acceptable solvent is polyethyleneglycol 400.
4. An oral solution as claimed in any of claims 1 to 3 wherein the taste modifying agent is an intense sweetener, a bulk sweetener, a flavouring agent, or a taste masking agent.
5. An oral solution as claimed in claim 4 wherein the taste modifying agent is an intense sweetener selected from the group consisting of saccharin, aspartame, acesulfame, cyclamate, alitame, a dihydrochalcone sweetener, monellin, neohesperidin, neotame, stevioside or sucralose (4,1',6'-trichloro-4,1',6'-trideoxygalactosucrose), and the pharmaceutically acceptable salts thereof.
6. An oral solution as claimed in claim 5 wherein the intense sweetener is present in an amount ranging from 0.1 to 10 mg/ml.
7. A oral solution as claimed in claim 6 wherein the intense sweetener is sucralose.

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8. An oral solution as claimed in any of claims 1 to 7 wherein the antioxidant is selected from the group consisting of BHA, BHT, propyl gallate, DL- α -tocopherol, and citric acid, and mixtures thereof.
- 5 9. An oral solution as claimed in claim 8 wherein the antioxidant is present in an amount ranging from 0.1 to 10 mg/ml.
10. An oral solution as claimed in claim 9 wherein the antioxidant is BHA.
- 10 11. An oral solution as claimed in claim 10 comprising 5 mg/ml mitratapide, sucralose in an amount ranging from 0.5 to 5 mg/ml, and BHA in an amount ranging from 1 mg/ml to 5 mg/ml, dissolved in PEG 400.
- 15 12. An oral solution as claimed in claim 11 comprising 5 mg/ml mitratapide, sucralose in an amount of 2 mg/ml, and BHA in an amount of 2 mg/ml, dissolved in PEG 400.
- 20 13. A process of preparing an oral solution as claimed in any of claims 1 to 12, characterized in that said process comprises the steps of dissolving mitratapide, the taste modifying agent and the antioxidant in the pharmaceutically acceptable solvent wherein mitratapide has a solubility of 5 mg/ml or higher at a temperature of 22°C, and stirring until a homogeneous solution is obtained.